



UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/215,212 | 12/18/98 | TEPPER | TEPPER=IA |

001444 HM12/1024
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EXAMINER
ANDRES, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1646 | 10 |

DATE MAILED: 10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/215,212

Applicant(s)

TEPPER ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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DETAILED ACTION

Response to Amendment

The amendment filed July 25, 200 (paper no. 7) has been entered in full. The sequence listing submitted contained non-ASCII "garbage" which was deleted on entry.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Objections/Claim Rejections Withdrawn

The objection to claims 1, 10, 22, and 23 is withdrawn in response to applicant's amendment correcting the misspelling and omission.

The rejection of claims 1-3 and 7-9 under 35 U.S.C. 103(a) is withdrawn in response to applicant's amendment to claim 1.

Claim Rejections Maintained/New Grounds of Rejection

The rejection of claims 10, 11, 15-17, and 21 under 35 U.S.C. 102(b) as being anticipated by either Cohen or the European patent to Yeda (EPO 588 177) is maintained and newly applied to claim 24. These claims are drawn to molecules "consisting essentially" of type I IFN and IFNAR. This language encompasses the addition of a radioactive iodine atom; this atom would not affect the "basic and novel characteristic" of p. 32. In addition, this language is not considered to be different from "comprising". Further, the '177 patent teaches a pharmaceutical composition comprising IFNAR2 (p. 2, lines 3 and 49, p. 6, lines 13-16, p.17, line 7), thus

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anticipating the molecules of claims 10, 11, 15-17, and the "pharmaceutically acceptable formulation" of claims 21 and 24.

Claims 12-14, 18-20, and 22 are newly rejected under 35 U.S.C. 102(b) as being anticipated by EPO 588 177. As stated above, '177 teaches a pharmaceutical composition comprising IFNAR2, anticipating claim 22. '177 further teaches pharmaceutical compositions comprising fused proteins (p.6, line 15), thus anticipating claims 12-14 and 18-20.

The rejection of claims 10, 11, 15-17, 21, and 22 under 35 U.S.C. 102(b) as being anticipated by Novick is maintained and newly applied to claim 24. Applicant argues that radiolabeled interferon is not encompassed in these claims. As stated above, the incorporation of a radioactive iodine atom is included in the "consisting essentially of" language. This language does not exclude other components.

Claims 1-24 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "type I IFN biological activity". As defined on p. 33, this term encompasses "the activity of the interferon relied upon for the intended utility" including agonist and antagonist activity. As stated on p.2, interferons are pleiotropic with many activities, including anti-proliferative activity, stimulation of cytotoxic activity, modulation of differentiation, and modulation of different receptors, with resulting anti-viral anti-parasitic, anti-tumor, and immune modulatory effects. The recitation of "biological activity" is therefore insufficient for one of skill in the art to be able to determine what activity is intended and thus what fragments, variants, and functional derivatives in combination with IFNAR would meet the limitations of the claims.

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NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

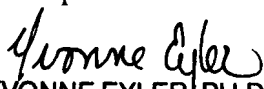
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
October 23, 2000


YVONNE EYLER, PH.D.
PRIMARY EXAMINER